

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Christoph-Stephan HILGER et al

Serial No.: Unassigned

Group Art Unit: Unassigned

Filed: July 25, 2003

Examiner: Unassigned

For: Radiopharmaceuticals For Diagnosing Alzheimer's Disease

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98**

**Mail Stop DD**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

**Timing and Fees**

- ☒ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
  - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
  - ☒ before the mailing of a first substantive office action (including after filing of an RCE).
- ☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- ☐ a final rejection under 37 C.F.R. 1.113;
  - ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
  - ☐ a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- ☐ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).
- ☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:
  - ☐ a final action under 37 C.F.R. § 1.113;
  - ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
  - ☐ a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

- ☒ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. 09/985,938; Filed: November 6, 2001, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated \_\_\_\_\_.
- ☐ Copies of the materials listed are attached (except for the foregoing).

### Non-English Language References

- ☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
- ☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:
- X = document of particular relevance when it is taken alone  
Y = document of particular relevance when it is combined with another such document  
A = document defining the general state of the art  
O = non-written disclosure  
P = intercalated document  
T = document cited to understand the theory or principle underlying the invention  
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date  
D = cited in the application  
L = cited for another reason  
& = publication of member of same patent family
- ☐ Translation of other relevant information on foreign search report


### Other Information

#### Payment of Fees Due (If Any):

- ☐ A check for \$\_\_\_\_\_ covering the fee identified above is attached.
- ☐ Please charge to Deposit Account No. 13-3402 \$\_\_\_\_\_ for the fee identified above.

☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

  
Brian P. Heaney, Reg. No. 32,542  
Attorney for Applicants

MILLEN, WHITE, ZELANO  
& BRANIGAN, P.C.  
Arlington Courthouse Plaza I  
2200 Clarendon Blvd. Suite 1400  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410

Attorney Docket No.: SCH-1834C1

Date: July 25, 2003

BPH:ikt

K:\Sch\1834\C1\7-25-03 IDS.doc

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		<b>Complete if Known</b>			
		Application Number	Unassigned		
		Filing Date	July 25, 2003		
		First Named Inventor	Christoph-Stephan HILGER et al		
		Group Art Unit	Unassigned		
		Examiner Name	K. Habte		
Sheet	1	of	2	Attorney Docket Number	SCH-1834C1

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	1	5,919,797		Goodman et al.	07/06/1999
	2	5,358,712		Efange et al.	10/25/1994
	3	5,721,243		Efange et al.	02/24/1998
	4	6,207,665	B1	Bauman et al.	03/27/2001
	5	5,286,728		Ferrini	02/15/1994

FOREIGN PATENT DOCUMENTS								
Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	6	FR	2 758 328	A1	Lamothe et al.	07/17/1998		Abs.
	7	WO	92/16239	A1	Parsons et al.	10/01/1992		
	8	WO	99/51594	A1	Katsifis et al.	10/14/1999		
	9	WO	98/02151	A2	Schwender et al.	01/22/1998		
	10	WO	96/01656	A1	Cliffe et al.	01/25/1996		
	11	WO	00/14086	A1	Luly et al.	03/16/2000		
	12	WO	00/42011	A1	Yamada et al.	07/20/2000		
	13	WO	00/58305	A1	10/05/2000			

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

<sup>1</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
		Application Number	Unassigned		
		Filing Date	July 25, 2003		
		First Named Inventor	Christoph-Stephan HILGER et al		
		Group Art Unit	Unassigned		
		Examiner Name	K. Habte		
		Attorney Docket Number	SCH-1834C1		
Sheet	2	of	2		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
H	14	K. Bergström et al., "Iodine-123 labelled Z-(R,R)-IQNP: a potential radioligand for visualization of M <sub>1</sub> and M <sub>2</sub> muscarinic acetylcholine receptors in Alzheimer's disease", European Journal of Nuclear Medicine, Vol. 26, No. 11, pp. 1482-1485, November 1999, XP-002193046	
	15	S. Oya et al., "Small and neutral Tc <sup>99m</sup> O <sub>4</sub> BAT, bisaminoethanethiol (N <sub>2</sub> S <sub>2</sub> ) complexes for developing new brain imaging agents", Nuclear Medicine & Biology, Vol. 25, pp. 35-140, 1998	
	16	A. Fischman et al., "Rapid detection of parkinson's disease by SPECT with altropane: A selective ligand for dopamine transporters", SYNAPSE, Vol. 29, pp. 128-141, 1998	
	17	J. Logan et al., "Graphical analysis of reversible radioligand binding from time-activity measurements applied to [N- <sup>11</sup> C-methyl]-(-)-cocaine PET studies in human subjects", Journal of Cerebral Blood Flow and metabolism, Vol. 10, pp. 740-747, 1990	
	18	J. Seibyl et al., "Iodine-123-β-CIT an diiodine-123-FPCIT SPECT measurement of dopamine transporter in healthy subjects and parkinson's patients", The Journal of Nuclear Medicine, Vol. 39, No. 9, pp. 1500-1508, September 1998	
	19	M. Melloul et al., "Double-Phase <sup>99m</sup> Tc-sestamibi scintimammography and trans-scan in diagnosing breast cancer", The Journal Of Nuclear Medicine, Vol. 40, No. 3, pp. 380, March 1999	
	20	J.L. Moretti et al., "Comparison of brain SPECT using <sup>99m</sup> Tc-Bicisate (L,L-ECD) and [ <sup>123</sup> I]IMP in cortical and subcortical strokes", Journal Of Cerebral Blood Flow And Metabolism, Vol. 14 (Suppl. 1), pp. S84-S90, 1994	
	21	J.M. Links, "Visual interpretation," Chapter 22 in HN Wagner et al. (Eds.), Principles of Nuclear Medicine, W.B. Saunders Company, 2 <sup>nd</sup> Edition, 1995, pages 391-392	
	22	EL Palmer et al. (Eds.), Practical Nuclear Medicine, Chapter 3 "Cardiovascular Imaging," W.B. Saunders Company, 1992, pp.71-120	
	23	International Search Report dated March 28, 2002.	

Examiner Signature	Date Considered
--------------------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.